DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 25 2007

• I-009006-P-0106

U.S. Department of Interior
Fish and Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Submission of information detailing the similarities between *Oncorhynchus* subspecies rainbow trout and steelhead trout

Dear Dr. Erdahl:

Based on the information in your submission dated February 9, 2007 and the information contained in the Investigational New Animal Drug (INAD) file 009006, the Division of Therapeutic Drugs for Food Animals considers the Effectiveness technical section for oxytetracycline medicated feed for the control of mortality in freshwater-reared *Oncorhynchus mykiss* due to columnaris disease associated with *Flavobacterium columnare*, when administered at a dose of 3.75 g oxytetracycline/100 pounds of fish/day for 10 consecutive days to be complete.

CVM agrees that the submitted information supports the claim that effectiveness data accepted for freshwater-reared steelhead trout has significant inferential value for other subspecies of *O. mykiss*. We have reviewed your submission dated February 9, 2007, in which you provided information that details the similarity between *Oncorhynchus* subspecies rainbow and steelhead trout. The submission contained information to support the claim that effectiveness data accepted for the label claim 'for the use of oxytetracycline medicated feed to control mortality due to columnaris disease associated with *Flavobacterium columnare* in freshwater-reared steelhead trout' could be expanded to include the claim 'for the use of oxytetracycline medicated feed to control mortality due to columnaris disease associated with *Flavobacterium columnare* in freshwater-reared *Oncorhynchus mykiss*.'

We agree that the genetic relatedness and culture condition similarities between rainbow trout and hatchery-reared steelhead trout (versus physiologically adapted steelhead trout) are sufficiently similar and therefore we believe conclusions about the effectiveness of oxytetracycline medicated feed to control mortality due to columnaris disease in hatchery-reared steelhead trout have inferential value for all subspecies of *Oncorhynchus mykiss*. Therefore, for the purposes of the label, we will amend the claim to read 'for the control of mortality due to columnaris disease associated with *Flavobacterium columnare* in freshwater-reared *Oncorhyncus mykiss*.' A summary of

the information from this submission will be included in the FOI summary with a statement which states that we consider this label claim to represent all subspecies of *O. mykiss* which include rainbow trout, steelhead trout, redband trout, and redband steelhead trout.

We also recommend that you perform an additional pivotal effectiveness study in the use of oxytetracycline medicated feed to control mortality due to columnaris disease in another salmonid species other than *O. mykiss* in order to get a claim for all freshwater-reared salmonids.

We will make a final decision on whether we can approve your application after we have reviewed all of the data for all applicable technical sections submitted in support of an Administrative New Animal Drug Application (NADA), NADA, or supplemental NADA, and any other information available to us, as a whole, and determined whether the requirements for approval set forth in the Federal Food, Drug, and Cosmetic Act have been met.

If you submit correspondence relating to your submission to the investigational file, you should reference this letter by date and the principal submission(s) identifier found at the top of this letter. If you have any questions, please contact me at (301) 827-7571 or Dr. Donald Prater, Leader, Aquaculture Drugs Team, at (301) 827-7567.

Sincerely,

Joan C. Gotthardt

Joan C. Gotthardt, D.V.M.
Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure:
Freedom of Information Summary